

HL7 SPL Working Group Process Team Telecon
Wednesday, August 20, 2008

Agenda:

- Discussion of process maps for DL and application processes using SPLr3 vs SPLr4
- OTC sub team update
- Generic sub team update
- Other sub team updates
- Webinar updates (Any new news?)
- AOB

Meeting Minutes:

Process maps for DL and application processes using SPLr3 vs SPLr4

Discussion of the three slides: the existing process flow, the process using R4, and the Phase 2 future process using R4 and a link between the Listing and the Application files.

In order for the linking to work, the application file does not have to be submitted via the ESG. The technical details of where the link will be provided are still in progress.

All SPL submitted through the Elist process will be available for download from the DailyMed site. No information currently available on whether the DailyMed site will make all SPL visible via their webpage.

Principal Display Panel section is not part of the Content of Label of the SPL, but is part of the SPL file. This section is where a JPG of cartons, etc. would reside.

For CBEs, SPL could be submitted simultaneously via the EList and the Application processes.

Drugs@FDA is a CDER site. It contains historic information, and tentative approval information. Generic labels are not generally posted on this site. Other divisions also have their specific label posting sites.

Facts@FDA will be a whole new website, and will include the current SPL files.

Subteam Updates

OTC Subteam:

Leads: Paula Markert Paula.T.Markert@gsk.com
Devon Morgan Devon.Morgan@perrigo.com

The team has had two meetings so far. They're pulling questions together, reviewing the draft guidance, and assessing people's understanding of SPL and what's involved.

In general, calls will be on alternating Mondays. For the week containing Labor Day, an alternate day/time is under discussion.

Generics Subteam:

Lead: Virginia Hogan Virginia.Hogan@tevausa.com

Minutes from the previous meeting

The team is reviewing the Draft Guidance. Comments from this group will include input from CHPA members, and be forwarded through CHPA to FDA.

Alternating Tuesdays for Generic team meetings.

Biologics Subteam:

Lead: Theresa Brunone theresa.m.brunone@gsk.com

For any specific questions about SPL, you can send an e-mail to SPL@fda.hhs.gov.

Our next Process Team meeting: September 3, 2008 1:00 – 2:30

Check out the SPL Working Group WIKI @: <http://spl-work-group.wikispaces.com>